

Food and Drug Administration Office of Regulatory Affairs**Summary Report****For Sample Number:** 163165**TD Sample Number:****Import Sample Number**

This is an accurate reproduction of the original electronic record as of 01/22/2013

Sample Class: Normal Everyday Sample**Sample Origin:** Domestic**Sample Basis:** Other-Compl**Sample Flag:** 301(k) Sample**Sample Type:** Official**Collecting District:** DET-DO**Home District:****Orig C/R and Records To:** NWE-DO**Collection PACs:** 56R814**Product Name:** Betamethasone Sodium Phosphate (Glucocorticoid); Human - Rx/Combination Ingredient; Active Pharm Ing**Product Description:** Betamethasone Repository (PF)**Collection Reason:** Sample request via OEO coordination (email) to DET-DO dtd 10/12/12 in response to the meningitis outbreak/epidural injections. Sample collected under PAC 56R814. Sterility analysis requested.

Lab: SAN- District LAB Conclusion: Disposition Reason:	Split Num: 0 District Conclusion Made By: Disposition Authorized By:	Date Received: 10/17/2012 Date Out of Lab: 01/22/2013 District Disposition Authorized Date:
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Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
SAN-MICRO	56R814		MIC		3 - Adverse Findings	Completed

Lab Conclusion

Bacillus lentus found in Sub 2, 5, 7.
Bacillus firmus found in Sub 6.
Bacillus pumilus found in Sub 9.
No growth observed from Sub 1, 3-4, 8, and 10.
Suitability tests satisfactory.
Controls satisfactory.

Lab Conclusion Date

01/22/2013

Lab Conclusion Made By

Lau, Henry K

DKL
acting LD
2/7/2013

FLAG Original

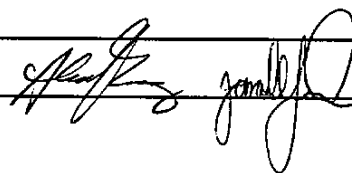
ANALYST WORKSHEET		1. PRODUCT Betamethasone Repos(PF) 6mg/ml injectable		2. SAMPLE NUMBER 163165	
3. SEALS Intact		4. DATE REC'D 10/17/2012		5. RECEIVED FROM James Gilchrist	
6. DISTRICT OF LABORATORY SANLAB					
7. DESCRIPTION OF SAMPLE One plastic bag officially sealed twice, once at the opening end of the bag id'd as "DET-DO 163165 10/15/12 MYRA K. CASEY, Investigator" and a second one on the closed end of the bag id'd as "DET-DO 163165 10/15/12 MYRA K. CASEY, Investigator", containing a total of 21 subs, subnumbered 1-21, each sub id'd as "163165 10/15/12 MKC". The sample was received intact at room temperature.					
8. NET CON-TENTS		☐ NOT APPLICABLE DECLARE/UNIT 5 ML ☒ NOT DETERMINED AMOUNT FOUND _____ _____ UNITS EXAMINED % OF DECLARED _____		9. LABEL-ING ORIGINAL(S) SUBMITTED 3 COPIES SUBMITTED LABELING NONE FOUND ☐ CODES NONE FOUND ☐	
10. SUMMARY OF ANALYSIS Container: Dark brown glass vial with silver top covered by a plastic red disk. The container measures ~4.5cm long x ~2cm wide. Labeling: Commercially printed on white gummy label. Manufacturer's name "NEW ENGLAND COMPOUNDING CTR", manufacturer's address "697 WAVERLY ST. FRAMINGHAM, MA 01702", manufacturer's phone number "800-994-6322", product description "BETAMETHASONE REPOS(PF) 6MG/ML IN...5 ML" lot number, expiration date, and preparation instructions "****SHAKE WELL****", amount. Product: White opaque liquid. Method and Analysis: See Methods Page 3. Results All controls satisfactory. <i>Bacillus lentus</i> isolated from subs 2, 5, and 7. <i>Bacillus firmus</i> isolated from sub 6. <i>Bacillus pumilus</i> isolated from sub 9. No growth detected in subs 1, 3, 4, 8, and 10. For system suitability see sample 756983 (attachment A)					
11. RESERVE SAMPLE Official seal at closed end of bag as id'd in item 7 above further id'd as "AKM 10/17/12" and left affixed to bag. Remainder of subs 1-10, and remaining packages in tact were identified as "163165 10/18/12 APL", placed in original packaging identified as "163165 10/18/12 APL" sealed as "163165 10/23/12 Andrew P. Lin", and returned to Jim Gilchrist, Sample custodian on 10/23/12. Samples were stored locked in room 165.					
12. ANALYST SIGNATURE					
Analyst(s)		Broke Seal Lead		Responsibilities	
Jon Yenovkian		☐ ☒		Sample analysis and writeup	
Andrew Lin		☐ ☐		sample analysis	
Alicia McKinsey		☒ ☐		Initial writeup	
Henry Lau		☐ ☐		Received sample	
Jenny.Yee		☐ ☐		Vitek carry though	
Teresa.Lee		☐ ☐		Vitek carry though	
Elaine.Yeh		☐ ☐		Turbidity carry though	
Eileen.Liu		☐ ☐		Turbidity carry though	
13. WORKSHEET CHECK a. BY b. DATE 1/22/13 14. DATE REPORTED 1/22/13					
Page 1 of 9 Pages					

e431 Attachments A-N

CODES	1. PRODUCT Betamethasone Repos(PF) 6mg/ml injectable	2. SAMPLE NUMBER 163165
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Commercially printed in black ink on label of subs 1-21 reads "Lot#08202012@44 Discard after 2/16/2013 GC"

Analyst(s)



Page 2 of 9 Pages

GENERAL CONTINUATION SHEET	PRODUCT Betamethasone Sodium Phosphate 6 mg/mL	SAMPLE NO. 163165
Please continue your entry below		
Methods:		
USP35-NF30 online, 2012, chapter <71> Sterility Tests, tested via direct inoculation		
Subs 1-10 analyzed individually.		
Procedure:		
Product was tested by direct inoculation. Product testing performed in a horizontal laminar flow hood certified in compliance with Class 100 conditions, located in a controlled environment clean room as described in Federal Standard No. 209E.		
Product of subs 1-10 were analyzed via direct inoculation as follows:		
The septum covered top of each tested sub was decontaminated by dipping it into a 10% bleach solution, allowing the top to air-dry for ~10 minutes, subsequently spraying with 70% sterile isopropanol, and allowing it to sit until dry in the horizontal laminar flow hood. A sterile needle and syringe was used to puncture the septum cap and withdraw the entire contents of the vial. One drop was of product was spread out on a plate of Malt Extract Agar (MEA), and the remaining amount of product, approximately 5 mL, was divided evenly by inoculating it into two 100 mL bottles of both Soybean Casein Digest (SCD) and Fluid Thioglycolate Medium (FT).		
For all subs tested, FT was incubated at 33± 2°C, SCD at 23±2°C, for 14 days, or until growth was observed.		
Media, environmental, system, and equipment controls run in parallel with sterility test:		
Two unopened vessels of each medium incubated in parallel with product test media, used as negative media control.		
Two opened vessels of each medium, two opened SCD agar plates, and two opened Potato Dextrose Agar plates were placed in working areas of the hood and a second of the described open media controls were placed on the bench-top during analysis. RODAC plates were used to test hood surface, bench surface, and floor of the clean-room, as well as the analysts' gloves and gowns, and two STA air sampling plates of the room environment during testing, all incubated in parallel as environmental controls.		
Two syringes with needles from the same sterilization lot used during analysis were used to withdraw SCD and FT, which were then incubated in parallel as negative equipment controls.		
ANALYST(S)	ANALYST NO.	PAGE 3 OF 9 PAGES

Isolate VITEK Record		PRODUCT	SAMPLE NO.			
Date Tested: November 1 st , 7 th , 14 th , and 20 th 2012		Betamethasone 6 mg/mL				
Isolate ID	Gram Stain ¹	VITEK Purity Check Saline ²	VITEK Purity Check Organism ³	VITEK / API 20E Results	VITEK Attachment(s)	Summary
163165 TSB7 colony 1	R+		P	Bacillus lentus	B	Organism Identified
163165 TSB7 colony 2	R+		P	Bacillus lentus	C	↓
163165 TSB7 colony 3	R+		P	Bacillus lentus	D	↓
B. subtilis	R+		P	Bacillus subtilis	E+F	Control Acceptable
163165 TSB6	R+		P	Bacillus firmus	G	Organism Identified
163165 TSB9	R+		P	Bacillus pumilus	H	↓
163165 Thio5	R+		P	Bacillus lentus	I	↓
B. subtilis control	R+		P	Bacillus subtilis	J+K	Control Acceptable
163165 Z TSB A	R+		P	Bacillus lentus	L	Organism Identified
B. subtilis control	R+		P	Bacillus subtilis	M+N	Control Acceptable
163165 FT5 5X 2/7/13	R+		P	Bacillus lentus	5X 2/7/13	—
163165 FT5 535X	C+		P	Staphylococcus epidermidis	carried over to next page	—
Saline Nov 1st 2/7/13		5X XNG			5X 2/7/13	Control Acceptable

ANALYST(S)

Jenny K. [Signature]

PAGE 6 OF 9 PAGES

- ¹ "+" = Gram Positive, "-" = Gram Negative, "R" = Rods, "C" = Cocci
² G = Growth, NG = No Growth
³ P = pure culture, M = mix culture, NG = No Growth

MICRO WS 4.17, V1.0 (Effective Date 12/7/12)

PRODUCT

Betamethasone 6mg/mL

SAMPLE NO.

JY 1/9/13

163162 163165

Sterility Agar Plate Control Daily Observation Record

= # of distinct colonies, SCD agar incubated @23±2° C on days 1-3 and 33±2° C on days 4 and 5.

"N" = No Growth PDA plates incubated @23±2° C for days 1-5

"T" = sample induced turbidity RODAC plates incubated @33±2° C for days 1 and 2.

"NC" = not checked

Negative Control	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Final results
Exposed SCD plates, hood	L	-	-	-	-	-	Bioburden below alert limits. Controls Acceptable
Exposed SCD plates, benchtop	R	-	-	-	-	-	
Air sampler (SCD agar)	R	-	-	-	-	-	
Exposed PDA plates, hood	2	1	1	1	1	1	
Exposed PDA plates, benchtop	L	-	-	-	-	-	
Exposed PDA plates, benchtop	R	-	-	-	-	-	
RODAC plates, hood	L	-	-	-	-	-	
RODAC plates, floor	R	-	-	-	-	-	
RODAC plates, wall	C	-	-	-	-	-	
RODAC plates, benchtop	L	-	-	-	-	-	
Analyst <u>APL</u> gloves	R	-	-	-	-	-	
Analyst <u>APL</u> arms and torso	A	-	-	-	-	-	Positive controls acceptable
Analyst <u>APL</u> head and thigh	T	-	-	-	-	-	
Analyst <u>JY</u> gloves	H	1	1	1	1	1	
Analyst <u>JY</u> arms and torso	L	-	-	-	-	-	
Analyst <u>JY</u> head and thigh	R	-	-	-	-	-	
Analyst <u>JY</u> arms and torso	A	-	-	-	-	-	
Analyst <u>JY</u> head and thigh	T	-	-	-	-	-	
Analyst <u>JY</u> arms and torso	H	-	-	-	-	-	
Analyst <u>JY</u> head and thigh	T	-	-	-	-	-	
Positive controls							
PDA inoculated w/ C. albicans	+						Positive controls acceptable
SCD inoculated w/ Paeruginosa	+						
RODAC inoculated w/ Paeruginosa	+						
Checking Date	10/19	10/20	10/21	10/22	10/23	10/24	
Analyst Initials	JY	JY	JY	JY	JY	JY	
Remarks							

Analyst(s)

Andr. J. L.

Page 8 of 9 Pages

PRODUCT	Betamethasone 6 mg/mL	SAMPLE NO.	163165
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Sterility QA Record

Media	Vol/ Unit	Autoclave No. or Lot No.	Reagent	Autoclave No. or Lot No.
Fluid Thioglycollate	100 mL	5112	Vitek GNI Cards	
Soybean Casein Digest	100 mL	5101	Vitek GP cards	98169512
Diluting Fluid A	100 mL		Vitek GN cards	98163559
Diluting Fluid D	100 mL		Vitek BCL cards	98181866
Rodac Plates	12 mL	5096	Saline for Vitek	98136269
SCD Plates	20 mL	5096 5144	Blood Agar	98184337, 98187823
SCD Slants	5 mL		Blood Agar	98187821, 98187822
PDA w/40 ppm chlortet	20 mL	5098	Blood Agar	98187816
MacConkey Plates	20 mL	5140	Gram stain kit	98163425
Air sampler plate	80 mL	5096	G 859. Saline	4485
Malt Extract Agar		5108, 12277 (Hardy)		
SCD broth	12243 (Hardy)			

Equipment	Autoclave No. or Lot No.
6-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	
3-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	
13 mm Swinney Unit with 0.22 µm filter and 20 Gauge needle	
3 cc syringes	4823
Air Sampler Probe	5117
Carboy	
Forceps	
Gown Sets	5117
Mop head	5118
Paper towels	
Scissors	
ATCC 6633 B. subtilis	043889
ATCC 16404 A. brasiliensis	160336
Microscope	1562

Analyst(s) Eric E. Smith John P. L. Jennifer K. Lee Page 9 of 9 Pages

MICRO STERILITY 10, V1.0 (Effective Date 3/14/2005)

Attachment A

163165

12/12/12

JY

GENERAL CONTINUATION SHEET		PRODUCT <u>Betamethasone SP 12 mg/mL</u>		SAMPLE NO. <u>756983</u>	
<u>BACTERIOSTASIS AND FUNGISTASIS</u>					
Date Started : <u>11/8/12</u>					
1. Procedure: less than 100 cells/spores each of test organisms 1, 2, 3, 5, & 6 were added to bottles containing <u>100</u> mL of Fluid Thioglycollate medium and <u>1</u> mL/gm product sample; less than 100 cells/spores each of test organisms 1, 2, 3, 4, & 5 were added to bottles containing <u>100</u> mL of Soybean Casein Digest medium and <u>1</u> mL/gm product sample. Both sets of media product were then incubated as in product sterility analysis. Similar sets of media without product were also inoculated as above and incubated with test bottles. 2. Modification: <u>P. aeruginosa, S. aureus, C. albicans, and C. sporogenes not tested.</u> <u>Performed post-analysis.</u> 3. Results: <u>Controls satisfactory.</u>					
Test Organisms	Media With Product		Media Without Product		
	Thio. 33°C	SCD 23°C	Thio. 33°C	SCD 23°C	
1. <i>Pseudomonas aeruginosa</i> ATCC# _____					
2. <i>Bacillus subtilis</i> ATCC# <u>6633</u> <u>Lot # 043689</u>	+	+	+	+	
3. <i>Staphylococcus aureus</i> ATCC# _____					
4. <i>Aspergillus niger</i> ATCC# <u>16404</u> <u>Lot # 160336</u>		+		+	
5. <i>Candida albicans</i> ATCC# _____					
6. <i>Clostridium sporogenes</i> ATCC# _____					
ANALYST(S) <u>P. L. P. L.</u>		<u>Jonathan Y. L.</u>		PAGE <u>6</u> OF <u>7</u> PAGES	

FORM FDA 431a (SAN-DO MICRO STERILITY4, V1.0) Effective Date 3/14/2006

Attachment B
U.S. FDA - San Francisco District

163165
11/1/12
TL

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 05:36 PDT
Autoprint

Isolate Group: 163165 TSB7 1L-1 **163165 TSB7 colony ①**

Bionumber: 1252105034110220
Selected Organism: Bacillus lentus

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 1, 2012 06:02 PDT	Status: Final	Analysis Time: 14.25 hours
Selected Organism	93% Probability Bacillus lentus Bionumber: 1252105034110220 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s) Bacillus lentus LeuA(71),APPA(3),NaCl 6.5%(12),			

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	-	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	+	34	dMLZ	(+)	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment C

U.S. FDA - San Francisco District

163165
11/1/12
TL
Autoprint

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 06:23 PDT

Isolate Group: 163165 TSB7 2-1

163165 TSB 7, colony ②

Bionumber: 1252105034110020

Selected Organism: Bacillus lentus

Comments:	
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Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 1, 2012 06:51 PDT	Status: Final	Analysis Time: 14.25 hours
Selected Organism	93% Probability Bacillus lentus Bionumber: 1252105034110020 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
Bacillus lentus LeuA(71),APPA(3),dMLZ(17).			

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	(+)	8	ProA	-
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	-	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	+	34	dMLZ	+	36	NAG	-	37	PLE	(-)	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment D

U.S. FDA - San Francisco District

163165
11/1/12
TL

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 06:23 PDT
Autoprint

Isolate Group: 163165 TSB7 3-1

163165 TSB7, colony ③

Bionumber: 1252105034110020

Selected Organism: Bacillus lentus

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 1, 2012 06:51 PDT	Status: Final	Analysis Time: 14.25 hours
Selected Organism	93% Probability Bacillus lentus Bionumber: 1252105034110020 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
Bacillus lentus LeuA(71),APPA(3),dMLZ(17),			

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	(-)	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	-	31	dMAN	(-)
32	dMNE	+	34	dMLZ	+	36	NAG	-	37	PLE	(-)	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	(-)	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

163165
11/1/12
TL

Attachment E
U.S. FDA - San Francisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 10:54 PDT
Printed by: LabTech

Isolate Group: B. subtilis-1

B. subtilis

Bionumber: 1372065605453261

Selected Organism: Bacillus subtilis

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 1, 2012 06:53 PDT	Status: Final	Analysis Time: 14.25 hours
Selected Organism	95% Probability Bacillus subtilis Bionumber: 1372065605453261 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate: Bacillus subtilis/amyloliquefaciens/atrophaeus Bacillus amyloliquefaciens Bacillus atrophaeus Bacillus subtilis			
Analysis Messages: See product information for additional information.			
Contraindicating Typical Biopattern(s) Bacillus subtilis/amyloliquefaciens/atrophaeus dmNE(88),GLYG(69),BGAL(25),INU(25),us			

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment F

U.S. FDA - San Francisco District

11/1/12
72

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 1, 2012 10:54 PDT
Printed by: LabTech

Isolate Group: B. subtilis-1 *B. subtilis*

Bionumber: 1372065605453261
Selected Organism: Bacillus subtilis

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	(-)	13	TyrA	+	14	BNAG	-
15	APPA	(-)	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	+	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	(+)	29	MTE	-	30	GlyA	(+)	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	+	53	dGLU	+	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment G
U.S. FDA - San Francisco District

163165
11/7/12
Jey

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 7, 2012 06:52 PST
Autoprint

Isolate Group: 163165 TSB 6-1

Bionumber: 0223101000010040

Selected Organism: Bacillus firmus

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 7, 2012 07:06 PST	Status: Final	Analysis Time: 14.00 hours
Selected Organism	95% Probability Bacillus firmus Bionumber: 0223101000010040 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
Bacillus firmus LeuA(87),APPA(6),dGLU(75).			

Biochemical Details																	
1	BXYL	-	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	-	10	PyrA	+	11	AGAL	-	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	-
43	BMAN	-	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	-	62	TTZ	+	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment H
U.S. FDA - San Francisco District

163165
11/7/12
Jug

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 7, 2012 06:52 PST
Autoprint

Isolate Group: 163165 TSB 9-1

Bionumber: 5256105614566261
Selected Organism: *Bacillus pumilus*

Comments:	
------------------	--

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 7, 2012 07:06 PST	Status: Final	Analysis Time: 14.00 hours
Selected Organism	93% Probability <i>Bacillus pumilus</i> Bionumber: 5256105614566261 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
<i>Bacillus pumilus</i> LeuA(79),APPA(17),AspA(5),POLYB_R(22),BMAN(22),			

Biochemical Details																	
1	BXYL	+	3	LysA	-	4	AspA	+	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	-	11	AGAL	+	12	AlaA	-	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	(+)	31	dMAN	+
32	dMNE	+	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	+	44	PHC	-	45	PVATE	+	46	AGLU	-	47	dTAG	+	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	+	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment I
U.S. FDA - San Francisco District

163165

11/7/12

guy

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 7, 2012 06:52 PST
Autoprint

Isolate Group: 163165 Thio 5-1

Bionumber: 4267105004010020
Selected Organism: Bacillus lentus

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 7, 2012 07:06 PST	Status: Final	Analysis Time: 14.00 hours
Selected Organism	89% Probability Bacillus lentus Bionumber: 4267105004010020 Confidence: Good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
Bacillus lentus LeuA(71),APPA(3),AspA(8),AlaA(15),BGAL(92),			

Biochemical Details																	
1	BXYL	-	3	LysA	-	4	AspA	+	5	LeuA	-	7	PheA	+	8	ProA	-
9	BGAL	-	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

163165
11/7/12
Jing

Attachment J
U.S. FDA - San Francisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 7, 2012 08:50 PST
Printed by: LabTech

Isolate Group: B. subtilis control-1

Bionumber: 1377141605552261

Selected Organism: Bacillus subtilis

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 7, 2012 07:05 PST	Status: Final	Analysis Time: 14.00 hours
Selected Organism	93% Probability Bacillus subtilis Bionumber: 1377141605552261 Confidence: Very good identification		
SRF Organism			
Analysis Organisms and Tests to Separate: Bacillus subtilis/amyloliquefaciens/atrophaeus Bacillus amyloliquefaciens Bacillus atrophaeus Bacillus subtilis			
Analysis Messages: See product information for additional information.			
Contraindicating Typical Biopattern(s) Bacillus subtilis/amyloliquefaciens/atrophaeus BNAG(19),dMNE(88),APPA(17),GLYG(69),BGAL(25),us			

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

163165
11/7/12
Jury

Attachment K
U.S. FDA - San Francisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Nov 7, 2012 08:50 PST
Printed by: LabTech

Isolate Group: B. subtilis control-1

Bionumber: 1377141605552261
Selected Organism: Bacillus subtilis

Biochemical Details

1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	+	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	(+)	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	(-)	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment L
U.S. FDA - San Francisco District

163165
12/10/12
JKY

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Dec 10, 2012 11:57 PST
Printed by: Labtech

Isolate Group: 163165 2 TSBA-1

(run 11/4/12 JKY)

Bionumber: 0067105004010020

Selected Organism: Bacillus lentus

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 4, 2012 08:39 PST	Status: Final	Analysis Time: 14.25 hours
Selected Organism	90% Probability Bacillus lentus Bionumber: 0067105004010020 Confidence: Good identification		
SRF Organism			
Analysis Organisms and Tests to Separate:			
Analysis Messages:			
Contraindicating Typical Biopattern(s)			
Bacillus lentus PheA(92),LeuA(71),APPA(3),BGAL(92),			

Biochemical Details																	
1	BXYL	-	3	LysA	-	4	AspA	-	5	LeuA	-	7	PheA	-	8	ProA	-
9	BGAL	-	10	PyrA	+	11	AGAL	+	12	AlaA	(+)	13	TyrA	+	14	BNAG	+
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	+	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	-	63	POLYB R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment M
U.S. FDA - San Francisco District

163165
12/10/12
JKY

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Dec 10, 2012 11:56 PST
Printed by: Labtech

Isolate Group: B. subtilis control-1

(run 11/4/12 JKY)

Bionumber: 1377161405556661

Selected Organism: Bacillus subtilis

Comments:	

Identification Information	Card: BCL	Lot Number: 239266620	Expires: Apr 2, 2014 13:00 PDT
	Completed: Nov 4, 2012 08:41 PST	Status: Final	Analysis Time: 14.25 hours
Selected Organism	91% Probability Bacillus subtilis Bionumber: 1377161405556661 Confidence: Good identification		
SRF Organism			
Analysis Organisms and Tests to Separate: Bacillus subtilis/amyloliquefaciens/atrophaeus Bacillus amyloliquefaciens Bacillus atrophaeus Bacillus subtilis			
Analysis Messages: See product information for additional information.			
Contraindicating Typical Biopattern(s) Bacillus subtilis/amyloliquefaciens/atrophaeus dMNE(88),APPA(17),KAN(6),GLYG(69),BGAL(25),GlyA(88),us			

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment N
U.S. FDA - San Francisco District

163165
12/10/12
Jky

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Dec 10, 2012 11:56 PST
Printed by: Labtech

Isolate Group: B. subtilis control-1

Bionumber: 1377161405556661

Selected Organism: Bacillus subtilis

Biochemical Details

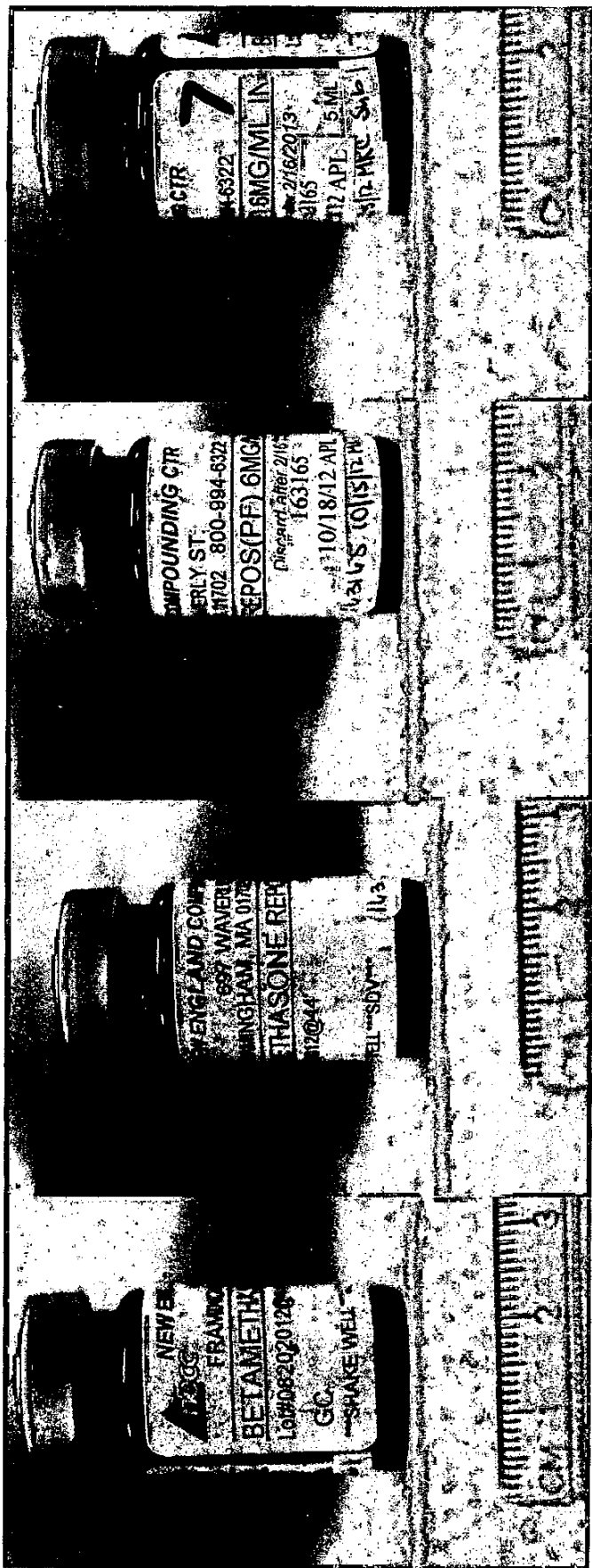
1	BXYL	+	3	LysA	-	4	AspA	-	5	LeuA	(+)	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	(+)
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	+	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	-	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	(+)	44	PHC	-	45	PVATE	+	46	AGLU	+	47	dTAG	-	48	dTRE	+
50	INU	-	53	dGLU	+	54	dRIB	+	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	+
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	+						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

labeling

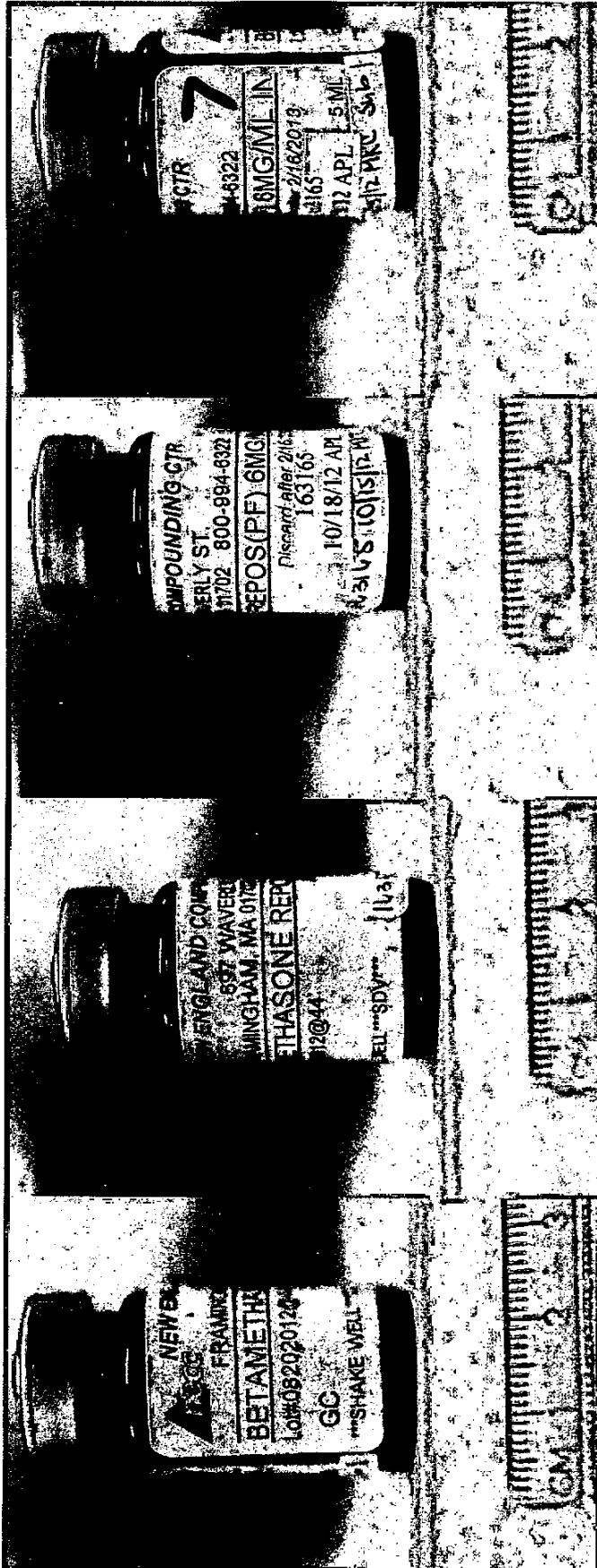
163165
10/23/12
apc



Picture verified by *[Signature]*
10/23/12

labeling

163165
10/23/12
apc



Picture verified by *[Signature]*
10/23/12

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 163165**

This is an accurate reproduction of the original electronic record as of 10/18/2012

Flag	Flag Remarks				
301(k) Sample					
Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Compln	Official	13206558	Completed
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3009804231	10/15/2012	64LDT07	Dealer	56R814	8
Compliance Num	Country of Origin				
	United States				
Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	DET-DO			Ambient
Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name	
No				New England Compounding Center	

Product Description

Betamethasone Repository (PF)

Product Label

See continuation.

Reason for Collection

Sample request via OEO coordination (email) to DET-DO dtd 10/12/12 in response to the meningitis outbreak/epidural injections. Sample collected under PAC 56R814. Sterility analysis requested.

MFG Codes

08202012@44

Expiration Date

2/16/2013

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	
Fort Wayne Physical Medicine	5750 Coventry Lane , Suite 101 Fort Wayne, IN 46804 US	Dealer	3009804231	
Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
21vials/bottles (6mg/ml-5ml per vial)	\$.00	FDA484	Federal Express	09/14/2012

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"163165 10/15/12 MKC" subs 1-21

Collector's Identification on Seal

"163165 10/15/12 Myra K. Casey"

Sample Delivered To

UPS South Bend, IN

Date Delivered

10/15/2012

Orig C/R & Records To

DET-DO

Lab w/Split Sample

0

Lab

SAN-LAB

Document Number	Document Date	Document Type	Document Remarks
FDA 484	10/15/2012	Other	Receipt for Samples
229015	09/12/2012	Other	Packing Slip
	10/15/2012	Affidavit	Affidavit obtained from Ms. Julie C. Risley, Physicians Assistant

Date: 10/18/2012

Page: 1 of 3

Food and Drug Administration Office of Regulatory Affairs**Collection Report****For Sample Number: 163165**

This is an accurate reproduction of the original electronic record as of 10/18/2012

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Myra K Casey
Name of Signer	Date & Time of Signature			Meaning
Myra K Casey	10/17/2012	03:09 PM	ET	Collector
Myra K Casey	10/16/2012	12:17 PM	ET	Collector

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 163165

This is an accurate reproduction of the original electronic record as of 10/18/2012

Continuation:

Product Label

Sample vials/ bottles labeled in part, "****necc *NEW ENGLAND COMPOUNDING CTR***697 WAVERLY ST.
FRAMINGHAM, MA 01702* 800-994-6322***BETAMETHASONE REPOS (PF) 6MG/ML IN***Lot #08202012@44***
GC***Discard after 2/16/2012*5ML***SHAKE WELL***SDV****"

Description of Sample

Sample consists of 21 unopened subsamples in brown glass vials/bottle with a red top with silver and paper label wrapped around bottle with product identification.

Method of Collection

21 vials/bottles were provided at collection in bubble pak and taped closed. Wrapped subs were placed in a brown paper bag with taped and sealed with FDA seals on 10/15/12 (attached). Sample was prepared for shipment and resealed on 10/16/12. Subs remained under lock and key from collection until shipment in cabinet at SBRP.

How Prepared

Each sub is identified as in Collector's ID On Package/Document, placed in a whirl pak bag and sealed with an FDA seals. Whirl pak bag wrapped in bubble pak and placed in bubble pak lined cardboard box. FDA 525 attached with sample request (email) dated 10/12/12, Packing Slip (Invoice #229015), Affidavit dated 10/15/12, photocopies and photos of subs and broken seals.

Remarks

The firm was unable to provide any shipping documents other than a Packing Slip (indicating invoice #229015) from New England Compounding Center (NECC) dated 9/12/12. I contacted Federal Express in order to obtain the tracking number and shipping documents associated with the shipment, however was told that there was no record of any shipments from NECC in Framingham, MA. The Packing Slip only indicates a PO box number. Ms. Julie C. Risley, attempted to call the NECC by phone and reached an answering service; she left a message. The firm has not yet returned her call; as a result, I/S shipping documentation will be obtained at a later date.

Estimated value of sample is currently unknown. The firm will provide information when person who handles monetary matters returns to the office.

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 163165

This is an accurate reproduction of the original electronic record as of 10/16/2012



Micro
MIC

163165

56R814

Flag

301(k) Sample

Flag Remarks

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Compln	Official	13206558	In Progress
FEI	Date Collected	Product Code	Responsible Firm	PAC	Hours
3009804231	10/15/2012	64LDT07	Dealer	56R814	
Compliance Num	Country of Origin				
	United States				

Related Smpl Num	Position Class	Sampling District	NDC Number	Permit Number	Storage Rqrmnt.
	INV	DET-DO			Ambient

Dealer is Consumer	Crx/DEA Schedule	Recall Num	Consumer Compl. Num	Brand Name
No				New England Compounding Center

Product Description

Betamethasone Repository (PF)

Product Label

See continuation.

Reason for Collection

Sample collected per a DET-DO DIB request dtd 10/12/12 in response to the meningitis outbreak/epidural injections. Sample collected under PAC 56R814. Sterility analysis requested.

MFG Codes

08202012@44

Expiration Date

2/16/2013

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	
Fort Wayne Physical Medicine	5750 Coventry Lane, Suite 101 Fort Wayne, IN 46804 US	Dealer	3009804231	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
21 vials/bottles (6mg/ml-5ml per vial)	\$.00	FDA484	Federal Express	09/14/2012

Description of Sample

See continuation.

Method of Collection

See continuation.

How Prepared

See continuation.

Collector's Identification on Package and/or Label

"163165 10/15/12 MKC" subs 1-21

Collector's Identification on Seal

"163165 10/15/12 Myra K. Casey"

Date	10/12/12
No. of Pkg.	1
Pkg. Type	BAG
Location	15-49B
Initials:	[Signature]
☐ Repacked by Sample Custodian	

Sample Delivered To

Federal Express South Bend, IN

Date Delivered

10/15/2012

Orig C/R & Records To

DET-DO

Lab w/Split Sample

0

Lab

SAN-LAB

Document Number	Document Date	Document Type	Document Remarks
229015	09/12/2012	Invoice	
	10/15/2012	Other	Affidavit obtained from Ms. Julie C. Risley, Physicians Assistant

Date: 10/16/2012

Page: 1 of 3

ANALYSES

☒ Microbiology	☐ Seafood Filth
☐ Decomposition	☐ Metals
☐ Chemistry	☐ Other

FDA_E00482725

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 163165

This is an accurate reproduction of the original electronic record as of 10/16/2012

Remarks

See continuation.

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
\$0.00	No Charge	No	No	Myra K Casey
Name of Signer	Date & Time of Signature	Meaning		
		ET		

Date: 10/16/2012

Page: 2 of 3

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 163165

This is an accurate reproduction of the original electronic record as of 10/16/2012

Continuation:

Product Label

Sample vials/ bottles labeled in part, "***necc *NEW ENGLAND COMPOUNDING CTR***697 WAVERLY ST.
FRAMINGHAM, MA 01702* 800-994-6322***BETAMETHASONE REPOS (PF) 6MG/ML IN***Lot #08202012@44***
GC***Discard after 2/16/2012*5ML***SHAKE WELL***SDV***"

Description of Sample

Sample consists of 21 unopened subsamples in brown glass vials/bottle with a red tops labeled as containing with 6mg/ml injection (5 ml per vial). Photographs and photocopies of vials attached. Sealed with FDA seals and FDA 525 attached.

Method of Collection

Vials/bottles were provided upon collection in bubble pak and taped closed. I placed the wrapped vials in a brown paper bag and closed with taped and sealed with FDA seals (attached). Sample remained in my possession until shipment under lock and key.

How Prepared

Each was identified as in Collector's ID, individually wrapped in bubble pak and placed in a box for shipment. Photocopies and photos of subs along with FDA 525 attached.

Remarks

The firm was unable to provide any shipping documents other than an invoice from New England Compounding Center (NECC) (invoice #229015 dated 9/12/12). I contacted Federal Express in order to obtain the tracking number and shipping documents associated with the shipment, however was told that there was no record of any shipments from NECC in Framingham, MA. The invoice only indicates a PO box number. Ms. Julie C. Risley, attempted to call the NECC by phone and reached an answering service; she left a message. The firm has not yet returned her call; as a result, I/S shipping documentation will be obtained at a later date.

Estimated value of sample is currently unknown. The firm will provide information when person who handles monetary matters returns to the office.

Casey, Myra

From: Haynes, Joseph
Sent: Sunday, October 14, 2012 8:09 PM
To: Campbell, Brian; Casey, Myra
Subject: RE: Meningitis outbreak/Epidural Injections/DET-DO sample collection at Fort Wayne Physical Medicine

Myra,

Please contact Julie Risley (info below) and collect this sample Monday morning. Please let me know if you have any issues.

Thank you,

Joe

Joseph Haynes

Supervisory Investigator
Food & Drug Administration
Detroit District Office
300 River Place, Suite 5900
Detroit, MI 48207
Office: 313-393-8258
Cell: 313-401-9152
Fax: 313-393-8139
Joseph.Haynes@fda.hhs.gov

From: Jasukaitis, Keith J
Sent: Friday, October 12, 2012 7:21 PM
To: Haynes, Joseph; Campbell, Brian; Casey, Myra
Cc: Jasukaitis, Keith J
Subject: Fw: Meningitis outbreak/Epidural Injections/DET-DO sample collection at Fort Wayne Physical Medicine

Can one of you contact the person below and arrange for sample collection asap? Please email me on any progress. Thx. KJ
Keith J. Jasukaitis

From: Malais, Tanya
Sent: Friday, October 12, 2012 12:48 PM
To: Jasukaitis, Keith J
Cc: Bass, Glenn; Czabaniuk, Art O.; ORAHQ ORS MANAGEMENT; Duran, Norma; FDA Emergency Operations; ORA HQ ERCG; Park, J Douglas; Jarman, Dwayne
Subject: Meningitis outbreak/Epidural Injections/DET-DO sample collection at Fort Wayne Physical Medicine

10/15/2012

163165
10/15/12
MKC


Good afternoon,

As you know, OEO is coordinating FDA's response to a Meningitis outbreak involving 170 cases in 11 states, including 14 deaths. CDER has identified additional NECC compounded products that they would like the field to collect for sterility testing. CDC notified OEO that Fort Wayne Physical Medicine is holding 21 bottles of NECC compounded Betamethasone, lot 08202012@44, for collection by FDA. Please contact Julie Risley at Fort Wayne Physical Medicine to arrange for the collection of this sample. The sample should be collected under PAC 56R814 and shipped to DEN-LAB for sterility testing. If the sample can be collected and shipped today, DEN-LAB is prepared to accept Saturday deliveries. The contact at DEN-LAB is Zachary Miller. Please provide the sample #, number of vials collected, and the UPS tracking number to FDA Emergency Operations and Zachary Miller as soon as the information is available. I understand that Fort Wayne is at least a 2 hour drive from any of your offices. So if the sample can be collected today, but not shipped, please provide FDA Emergency Operations with the sample # and number of vials collected. If the sample cannot be collected today, please contact Ms. Risley to request she hold the product until it can be collected.

Contact information:

Julie Risley

Fort Wayne Physical Medicine

5750 Coventry Lane Fort Wayne, IN 46804
(260) 436-9337

If you have any questions or I can be of any assistance, please let me know.

Tanya E. Malais

Emergency Coordinator

OCM/Office of Emergency Operations

Food & Drug Administration

Irvine, CA

Office: 949-608-2984

Cell: 202-495-8565

Fax: 949-608-4401

e-mail: Tanya.Malais@fda.hhs.gov

24 hour emergency line: 866-300-4374 or 301-796-8240

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163165
10/15/12
MKC


10/15/2012

AFFIDAVIT		SAMPLE NO. <u>163145</u>
STATE OF <u>Indiana</u>	COUNTY OF <u>Allen</u>	
Before me, <u>Mym K. Casey</u>, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared <u>Julie C. Risley</u> in the county and state aforesaid, who, being duly sworn, deposes and says:		
I am Julie C. Risley, Physician Assistant at Fort Wayne Physical Medicine, 5750 Coventry Lane Suite 101, Fort Wayne, IN 46804. I have knowledge of the ~~receipt~~ ^{receipt} and use of products from New England Compounding Center ^{697 Waverly St.} Framingham, MA., including Betamethasone Repository (PF) 6mg/ml, 5ml per vial/bottle. On 10/15/12, Mym K. Casey of the US Food and Drug Administration collected 21 vials/bottles of Betamethasone Repository (PF) 6mg/mL (5ml per vial), of lot # 08202012 @ 44 that was shipped from New England Compounding Center.		
AFFIANT'S SIGNATURE AND TITLE <u>Julie C. Risley PA</u>		
FIRM'S NAME AND ADDRESS (Include ZIP Code) <u>Fort Wayne Physical Medicine</u> <u>5750 Coventry Lane Suite 101 Fort Wayne, IN 46804</u>		
Subscribed and sworn to before me at <u>Fort Wayne, IN</u> (City and State) this <u>15th</u> day of <u>October</u>, 2012.		
<u>Mym K. Casey</u> (Employee's Signature)		
Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.		

AFFIDAVIT

SAMPLE NO.

163165

STATE OF

Indiana

COUNTY OF

ALLEN

Before me, ~~Myra K. Casey~~ Myra K. Casey, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Julie C. Risley in the county and state aforesaid, who, being duly sworn, deposes and says:

Currently, four (4) vials of this lot were used between 9/14/12 and 10/1/12. We have had no patients contacting us with any meningitis type symptoms to this point. We have not contacted any patients who have received this medication at this point ~~due~~ due to the CDC guidelines.

I hereby acknowledge that the aforementioned information is true to the best of my knowledge.

AFFIANT'S SIGNATURE AND TITLE

Julie C. Risley RAC

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Fort Wayne Physical Medicine
5750 Coventry Lane Suite 101 Fort Wayne, IN 46804

Subscribed and sworn to before me at Fort Wayne, IN (City and State)

this 15th day of October, 2012

Julie C. Risley RAC (Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.



New England Compounding Center, Inc.
PO Box 4146
Woburn, MA 01888-4146
Ph. 508-820-0606
Fx. 508-820-1616

Packing Slip

Date	Invoice #
9/12/2012	229015

Ship To
FORT WAYNE PHYSICAL MEDICINE 5750 COVENTRY LANE SUITE 101 FORT WAYNE, IN 46804 ATTN: JENNI RHODEHAMEL

P.O. No.	Ship	Via	FOB	Project
	9/12/2012	FEDEX		

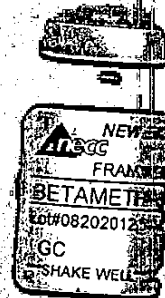
Quantity	Item Code	Description
25	BETA 6/5 PF	BETAMETHASONE REPOSITORY INJ. (PF) 6MG/ML, 5 ML
1	Shipping Charges	

*Rec'd
9/14/12
per WW*

!!!THANK YOU FOR YOUR ORDER!!!

PLEASE PLACE INVOICE NUMBER ON PAYMENT

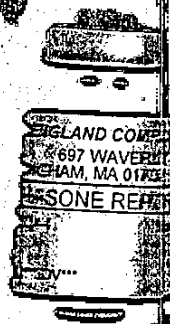
163165
10/15/12
MKC
JE



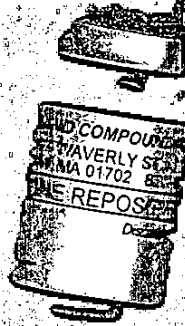
163165
10/15/12
MKC

NEW ENGL
FRAMING
AMETHAS
202012@44
WELL

163165
10/15/12
MKCME

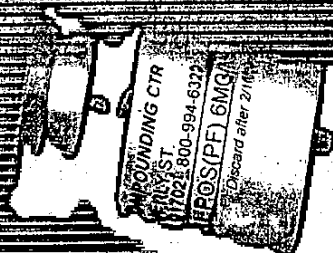


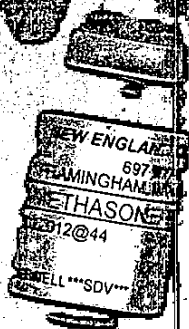
163165
10/15/12
MKCH/E



163165
10/15/12
MKC *ME*

163165
10/15/12
MKC *mkc*

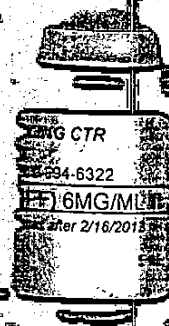




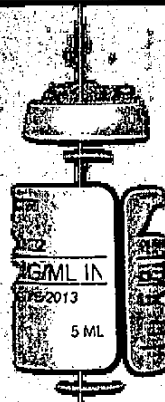
163165
10/15/12
MKQWZ

ENGLAND CO
697 W
INGHAM, MA
PHASONE
@44
SDV

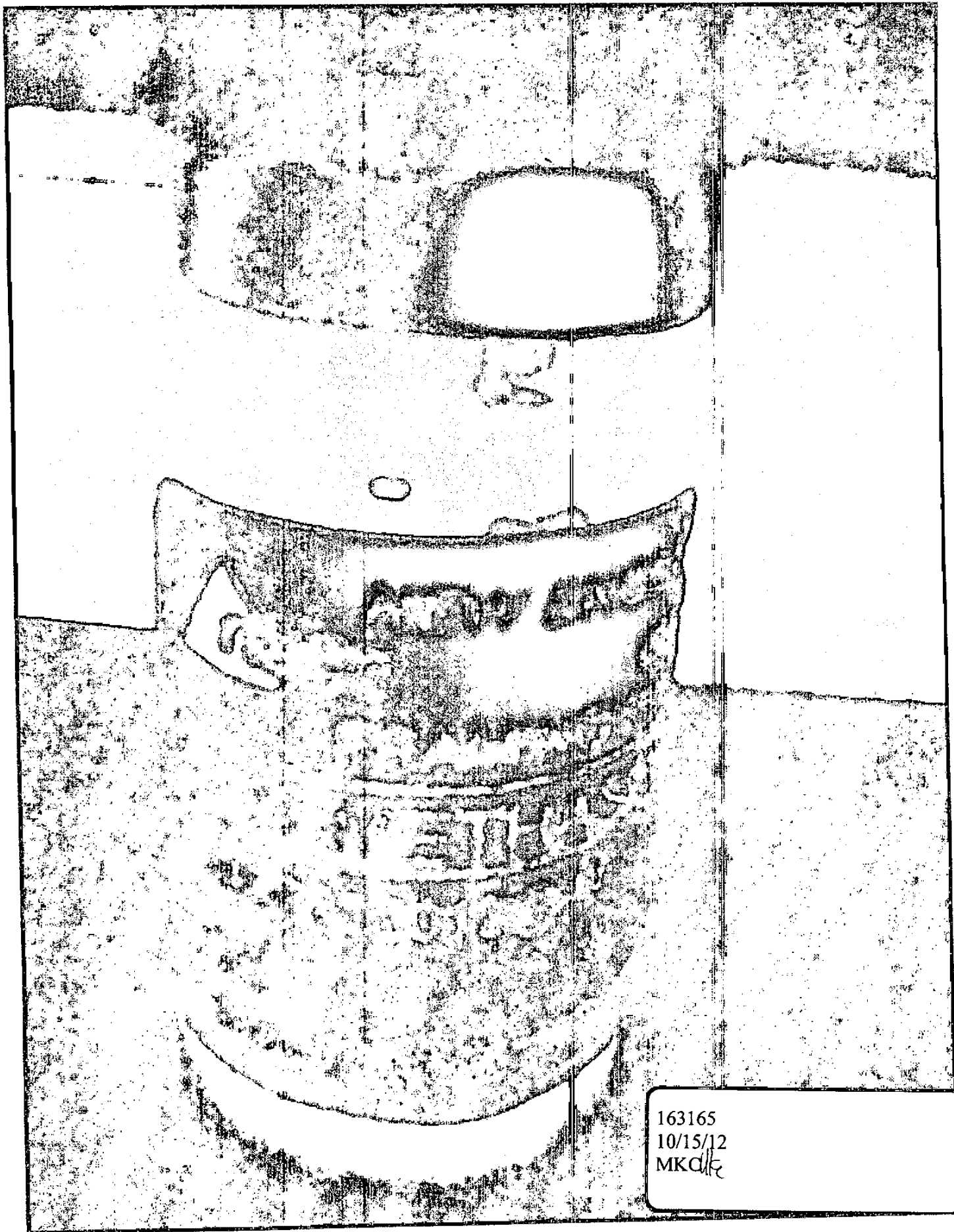
163165
10/15/12
MK



163165
10/15/12
MKC *u/k*



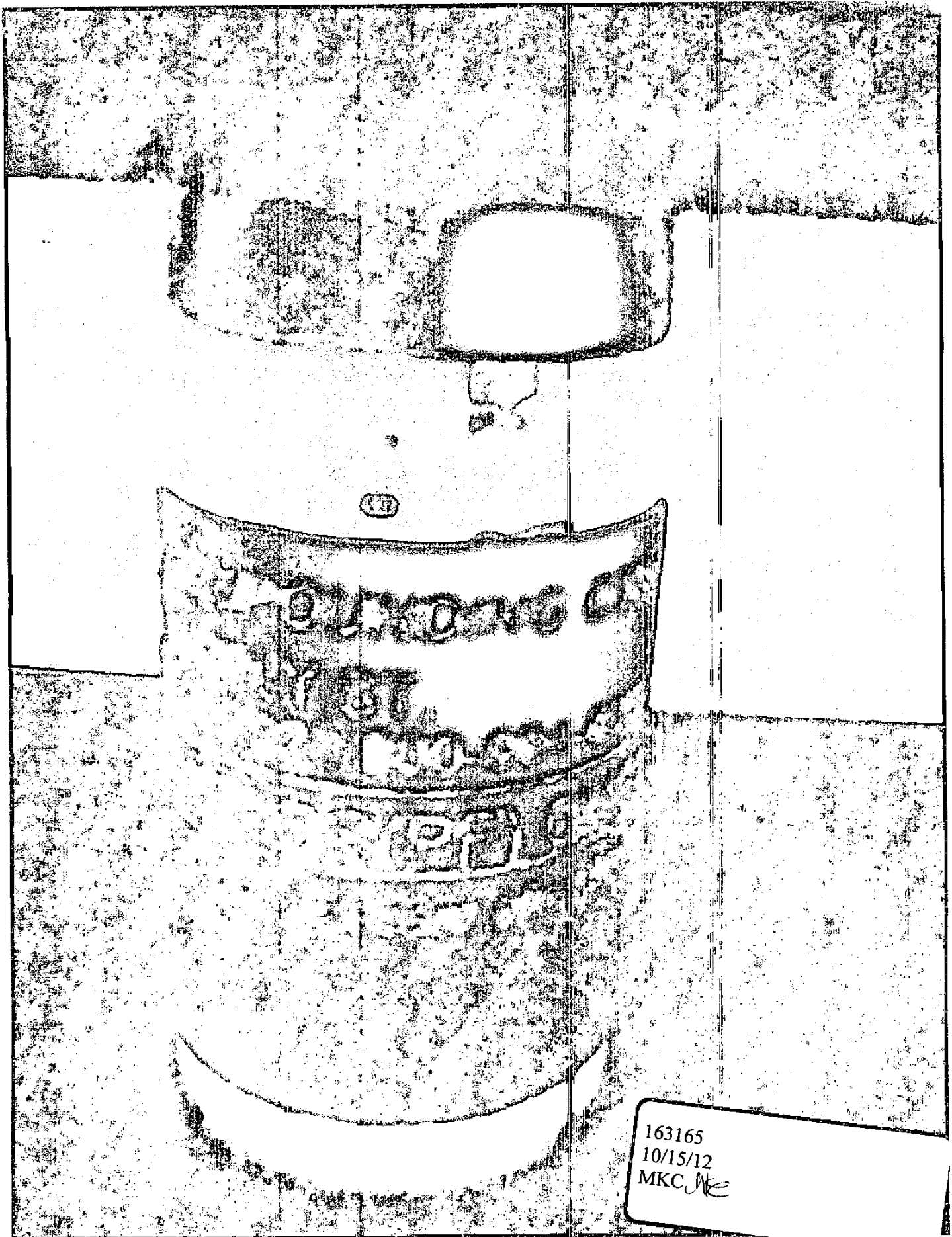
163165
10/15/12
MKCVR



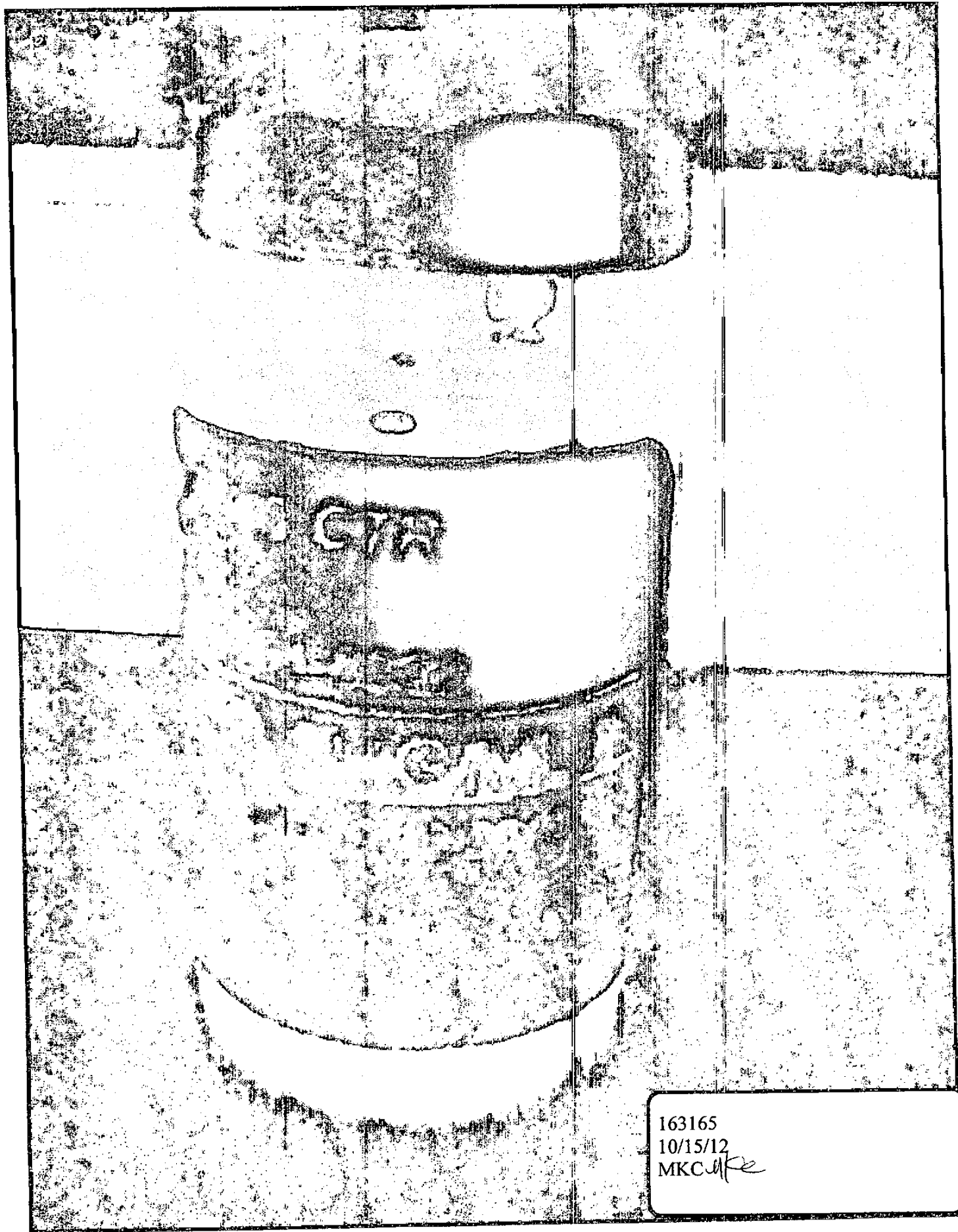
163165
10/15/12
MKD/fe



163165
10/15/12
MKCM/e



163165
10/15/12
MKC *ME*



163165
10/15/12
MKC *ulfe*

163165
10/15/12
MKC

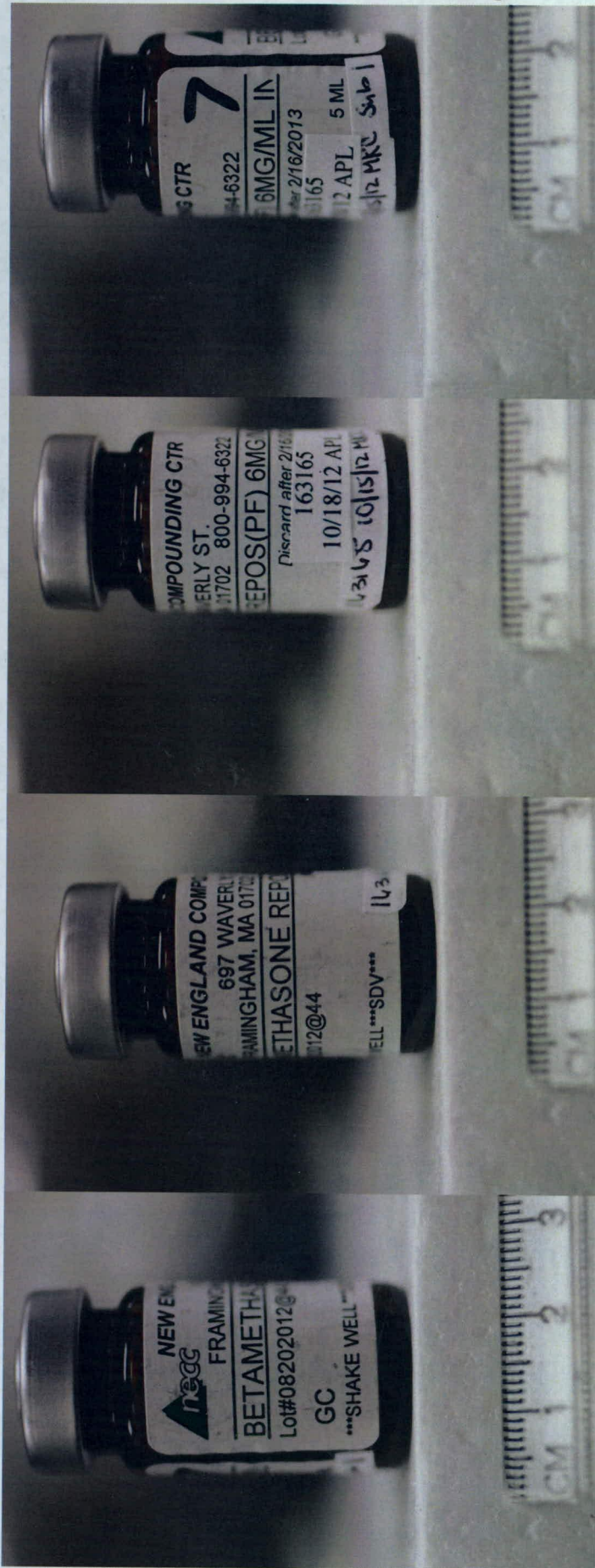
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDER
10/15/12

1-800-555-6518
FEDERAL BUREAU OF INVESTIGATION
U.S. DEPARTMENT OF JUSTICE

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CDER
10/15/12
SAMPLE NO. 163165
PRINTED NAME & TITLE
NAME & TITLE

labeling

163165
10/23/12
apc



Picture verified by *LoL*
10/23/12

1. TO: U.S. FOOD AND DRUG ADMINISTRATION		2. DATE
CITY: STAN-DOUGLAS	STATE:	10/16/12
3. FROM: (District, Division or Unit and Symbol)		4. SAMPLE NUMBER
DET-DO		163165
5. FIRM NAME		6. PRODUCT
Fort Wayne Physical Medicine Fort Wayne, IN		Betamethasone Repo (PF)
7. FIRM ADDRESS (Include Zip Code)		
6750 Coventry Lane Ste 101 Fort Wayne IN 46804		
8. REASON FOR COLLECTION (Copy from C/R)		9. ANALYSIS DESIRED
Sample request via CEO coordination (email) to DET-DO dtd 10/11/12 in response to the meningitis outbreak epidemiologic section.		Sterility
10. REMARKS		11. STORAGE INSTRUCTIONS
		☐ REFRIGERATE AT _____ °F ☐ KEEP FROZEN ☒ KEEP AT ROOM TEMP ☐ OTHER (Specify in remarks)
Package 1 of 1 Packages		12. INSPECTOR-INVESTIGATOR
		Myra K. Casey

FORM FDA 525 (4/06) PREVIOUS EDITION MAY BE USED

SAMPLE PACKAGE IDENTIFICATION

INSTRUCTIONS

1. Fill out all blocks completely and accurately following the instructions/precautions given in IOM section 4.5.5 and firmly glue flap closed.
2. If this envelope is used as a sample package for small items, place Form 415a "Seal" across flap and face of this form and attach another 525 "back-to-back" for any paperwork related to the sample.